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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,543	10/13/2004	Kjell Olmarker	003301-175	1315
21839 7590 12/20/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER MONDESI, ROBERT B	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 12/20/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/506,543

Applicant(s)

OLMARKER, KJELL

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-48 is/are pending in the application.
- 4a) Of the above claim(s) 24-45, 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

This Office action is in response to the amendment filed October 22, 2007.

### *Status of the Claims*

**Claims 1-24** have been canceled. **Claims 25-48** are currently pending. **Claims 25-45 and 47-48** are withdrawn for pertaining to non-elected subject matter. **Claim 46** is presently under examination.

### *Withdrawal of Objections and Rejections*

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed October 22, 2007.

### *Maintenance of rejections*

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 46** remains rejected under 35 U.S.C. 102(e) as being anticipated by

Reuben et al. United States Patent Application Publication US 2002/0072596.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 46** remains rejected under 35 U.S.C. 103(a) as being unpatentable over Mita et al. US Patent No. 5,561,109 in view of Rekdal et al., 1999.

Mita et al. teach a method of treating wounds, which includes the administering of lactoferrin (claim 1 of US. Patent No. 5,561,109).

Mita et al. do not teach the administering of lactoferrin derivatives.

Rekdal et al. teach lactoferrin derivatives and the enhanced antimicrobial activity of lactoferrin derivatives in comparison to lactoferrin (page 33, column 1, lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to create lactoferrin derivatives for the advantages of increasing lactoferrins' antimicrobial activity as taught by Mita et al. and Rekdal et al., see Rekdal et al. at page 33, column 1 lines 1-14.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claim 46** is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1 and 23** of copending Application No. 10/092,919.

The above rejections were explained in Office action mailed February 8, 2007.

#### ***Response to applicants' arguments***

In regards to the rejection of **claim 46** under 35 U.S.C. 102(e) as being anticipated by Reuben et al., applicants assert that **claim 46** has been amended to recite that the peptides derived from lactoferrin are those found at amino acid 12 to amino acid 40 of human lactoferrin and as previously noted, Ruben does not disclose peptides derived from amino acid 12 to amino acid 40 of human lactoferrin. Ruben further distinguishes between polypeptides and polypeptide fragments. Thus, Ruben does not disclose the peptide derivatives recited by the present claims.

Applicants' arguments have been considered but have not been found persuasive because the amendment to **claim 46** does not allow the examiner to

comprehend which portion of the lactoferrin peptide the applicants are referring to. Furthermore "derived from" is not the same type of transitional phrase as "is", "set forth", "consists of" or even "comprises", see rejection of claims under 35 U.S.C. 112, second paragraph- below. The broadest reasonable interpretation of the claims allows for the citation of the above reference as prior art and as stated in the previous Office action, the applicants themselves have clearly stated on the record that Ruben discloses transferring sequences, two of which SEQ ID NO: 4 and SEQ ID No: 6 that can be derived from lactoferrin, see remarks page 1, paragraph 4, lines 1-2 in amendment filed March 26, 2007.

In regards to the rejection of **claim 46** under 35 U.S.C. 103(a) as being unpatentable over Mita et al. US Patent No. 5,561,109 in view of Rekdal et al., 1999., applicants assert that the Office acknowledges that Mita fails to disclose the administration of lactoferrin derivatives, and thus cites Rekdal as purportedly disclosing lactoferrin derivatives having enhanced microbial activity. However, Rekdal does not teach or suggest that peptides as set forth in WO 00/01730, as incorporated by reference and set forth in the present specification.

Applicants' arguments have been considered but have not been found persuasive. The inappropriate incorporation of WO 00/01730 has been addressed in the above rejection and below in the New Rejection(s) and Objection(s) section of the instant Office Action.

In regards to the provisional rejection of claim 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1 and 23** of

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copending Application No. 10/092,919 applicants have asserted that a Terminal Disclaimer will be filed once allowable subject matter has been determined.

***New Rejection(s) and Objection(s)***

***Specification***

This application contains sequence disclosures at page 10, lines 11-12 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier- attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

The amendment filed October 22, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have attempted to amend the specification in order to incorporate **essential material** that is disclosed in an International application (WO 00/01730). However it appears that applicants have misinterpreted examiners' citation of rule 1.57(f). Careful note must be made in reference to the distinction between **essential material** and **material**. Per rule

1.57(c): "Essential material" may be incorporated by reference, but **only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication**, which patent or patent application publication does not itself incorporate such essential material by reference. "**Essential material**" is material that is necessary to: (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112; (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the reply to this Office Action.

As indicated by the previous citation of rule 1.57(f), applicants may incorporate **material** (non-essential) by way of amendment to the specification as long as a statement accompanies the amendment that the **material** is not new matter. Clearly, presently applicants have attempted to amend the specification in order to incorporate **essential material**, see amendment to **claim 46**; therefore this is not an accepted amendment to the specification because it has raised issues with regards to new matter.



***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 46** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is specifically a new matter rejection. Applicants' amendment to **claim 46** has introduced new matter to the claimed invention. As mentioned above the incorporation by reference to an international application is not the same as incorporation by reference to a US Patent or US Patent publication; therefore as a consequence applicants cannot introduce **essential material** that was previously disclosed in WO 00/01730 by way of reference. In this particular situation applicants have attempted to characterize the amino acid sequence of a peptide fragment derived from lactoferrin. Presently, the question is raised as to whether applicants' amendment to claim has raised new issues with regards to new matter. The failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the

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claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.

**Claim 46** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended **claim 46** in order to introduce the language, a peptide derived from "amino acid 12 to amino acid 40 of human lactoferrin". Unfortunately there is no way the examiner can know what particular amino acid residues are being referred to because there is no point of reference for any specific residue. Since there is no point of reference that the examiner can use, amino acids 12-40 can be any amino acids of a lactoferrin peptide so long as the mentioned peptide is 18 residues long. Furthermore, the claim states that the peptide is derived from and not "is", "set forth as", "consists of" or even "comprises", the residues 12-40 of lactoferrin. A person of ordinary skill in the art would not be able to know the sequence of the mentioned peptide without further clarification. The examiner had previously suggested the submission of a SEQ ID NO: in order to overcome this particular rejection; however applicants have so far not complied with the examiner's request.

### **Conclusion**

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/  
Examiner  
Art Unit 1652  
November 26, 2007